

manufactured or processed under essentially the same conditions. The term shall mean “inspection lot,” i.e., a collection of units of product from which a sample is to be drawn and inspected to determine conformance with the acceptability criteria. An inspection lot may differ from a collection of units designated as a lot for other purposes (e.g., production lot, shipping lot, etc.).

Lot size. The number of units in the lot.

Operating characteristic curve (OC curve). A curve that gives the probability of acceptance as a function of a specific lot quality level.

Probability of acceptance (Pa). For a given sampling plan and a given quality of inspection lots, is that percentage of inspection lots expected to be accepted.

Process capability. Performance of a process under normal operating conditions. The performance is measured with respect to specific characteristics.

Producer’s risk. The risk that a producer takes that a lot will be rejected by a sampling plan even though the lot conforms to requirements. In the standards of this subpart this risk is nominally set at five percent.

Random sampling. A process of selecting a sample from a lot whereby each unit in the lot has an equal chance of being chosen. Ordinary haphazard choice is generally insufficient to guarantee randomness. Devices such as tables of random numbers are used to remove subjective biases inherent in personal choice.

Rejection number (Re). The number in a sampling plan that indicates the minimum number of defects or defectives permitted in a sample that will cause a lot to fail a specific requirement.

Sample. Any number of sample units which are to be used for inspection.

Sample size. The number of sample units which are to be included in the sample.

Sample unit. A container, the entire contents of a container, a portion of the contents of a container, a composite mixture of a product, or any other unit of container or commodity to be used for inspection.

Sampling. The act of drawing or selecting sample units from a given lot.

Sampling plan. A specific plan which states the sample size(s), acceptance number(s) and rejection number(s). In the standards of this subpart two types of sampling plans are provided:

(a) *Single sampling plan.* A sampling inspection scheme in which a decision to accept or reject an inspection lot is based on the inspection of a single sample. A single sampling plan consists of a single sample size with associated acceptance and rejection number(s).

(b) *Double sampling plan.* A sampling inspection scheme which involves use of two independently drawn but related samples, a first sample (n_1) and a second sample which is added to the first to form a total sample size (n_2). A double sampling plan consists of a first and total sample size with associated acceptance and rejection number(s). Inspection of the first sample leads to a decision to accept, to reject, or to take a second sample and the examination of a second sample, when required, always leads to a decision to accept or reject.

SAMPLING PLANS

§ 43.103 Purpose and scope.

(a) This subpart contains selected single and double sampling plans for inspection by attributes. They are to serve as a source of plans for developing sound specifications, standards, or sampling and inspection procedures.

(b) The sampling plans of this subpart and corresponding operating characteristic curves are indexed by acceptable quality level, AQL. The AQL’s expressed in percent defectives or defects per hundred units are:

0.065	0.40	2.5	8.5
0.10	0.65	4.0	10.0
0.15	1.0	5.0	12.5
0.25	1.5	6.5	15.0

§ 43.104 Master table of single and double sampling plans.

(a) In the master table, a sampling plan is selected by first determining the sample size or sizes and AQL to be used. Then find the applicable acceptance (A_c) and rejection (R_e) numbers at the intersection of the sample size(s) row and AQL column. These numbers together with the sample size or sizes constitute a sampling plan.

(b) Single sampling plans having a sample size of 66 or greater and an acceptance number of 1 are not included in the Master Table. These plans are listed in the tables which supplement the Master Table and accompany the OC curves as indexes to the comparable double sampling plans. The use of these single sampling plans do not facilitate the practice of using two or more AQL's simultaneously with the same sample size.

§ 43.105 Operating characteristics (OC) curves.

The OC curves shows the ability of the various sampling plans, presented for each AQL, to distinguish between lots of different quality.

§ 43.106 Choosing AQL's and sampling plans.

(a) The selection of AQL's and sampling plans for given lot sizes depends on too many factors to permit the issuance of a "pre-selected" standard set of plans for specified lot sizes. Each user of the standards of this subpart should select AQL's and sampling plans that are tailored to best meet his needs.

(b) Some of the factors that must be considered prior to selecting the AQL's are:

(1) Class of defects such as major and minor: Major defects would generally require lower AQL's than those for minor defects;

(2) Process capabilities under good commercial practice with respect to the defects in question: For example, if under normal production processes, the defect level cannot be kept below 2.0 percent defective, the selection of an AQL of 0.15 percent defective, although desirable for the defects in question, may not be practical;

(3) Consumer preferences: These may require higher AQL's or permit lower

AQL's than process capabilities would indicate; and

(4) Time and cost required to sample and inspect a lot under various AQL's: The smaller the AQL the more time and cost of inspection.

(c) Some of the factors that may be considered prior to selecting the sampling plans for given lot sizes are:

(1) The applicable AQL(s): The AQL dictates, among other things, the smallest sample size that can be used and the size of the "jumps" from one sample size to the next larger one;

(2) The relative ability of the plans to discriminate between "good" and "bad" lots: Although several plans in these standards have the same AQL, they differ in their ability to reject lots worse than the AQL's. The OC curve in the standards of this subpart provide the basis for determining the discriminating ability of each plan;

(3) The amount, time, and cost of sampling required;

(4) The size and value of the lots relative to the producer and consumer protection a sampling plan affords: One may be willing to take larger risks of passing "bad" lots that are small or of lesser value than they would for larger more valuable lots;

(5) The knowledge about the lot(s) to be submitted for inspection: Lots consisting of product produced under essentially the same conditions may require smaller sample sizes than those consisting of product produced by different shifts and different raw stock for example; and

(6) The record of the quality level of previously submitted lots: The sample size can be smaller for lots submitted from a supplier with a consistent record of quality levels significantly better than the specified AQL(s) than sample sizes for the supplier whose records show considerable variability in quality, "borderline" supplies or product worse than the AQL.